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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/601,138	10/26/00	FOGH	J FOGH1

EXAMINER

HM12/0309

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WASHINGTON DC 20004

ART UNIT	PAPER NUMBER
1652	6

DATE MAILED: 03/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/601,138	FOGH ET AL.	
	Examiner	Art Unit	
	Malgorzata A. Walicka	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *26 October 2000* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32 and 35-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-32 and 35-46* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

The examiner acknowledges the application and the first amendment filed on October 26, 2000. The corrections to claims were entered as requested, claims 33-34 were cancelled. According to Applicant's wish claims were renumbered starting with the second claim 36; the appropriate renumbering was entered of dependencies in claims referring to claims originally numbered 37-45. Claims 1-32, 35-46 are pending in the application and subject of this Office action.

Restriction/Election

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-37, drawn a conventional treatment or prophylaxis of disease caused by deficiency of an enzyme belonging to the heme biosynthetic pathway

Group II, claim(s) 38-46, drawn to gene therapy of disease caused by deficiency of an enzyme belonging to the heme biosynthetic pathway .

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Invention of Group I relates to the treatment of afflicted subjects by appropriate enzyme which is combined with a pharmaceutically acceptable carrier and administered intravenously, intraarterially, buccally, intramuscularly, by anal, transdermic, intradermal and intratechal route.

Invention of Group II relates to the treatment of afflicted subjects by transfecting them with cDNA sequence of appropriate enzyme, so that expression of the normal protein elevated the syndrome.

The technical features of both groups are different; therefore, the invention as claimed lacks the single general invention concept. Restriction as indicated above is proper.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In order for more than one species to be examined, the appropriate additional examination fees must be paid. The species are as follows:

1. acute intermittent porphyria (AIP) and porphobilinogen deaminase (PBGD)

2. ALA deficiency porphyria (ADP) and ALA dehydratase,

3. porphyria cutanea tarda (PCT) and uroporphyrinogendecarboxylase,

4. hereditary coproporphyria (HCP)and harderoporphyria (HDP) and coproporphyrinogen oxidase,

5. variegata porphyria (VP) protoporphyrinogen oxidase,

6. congenitial erythropoetic porphyria (CEP) and uroporphyrinogen III synthase,

7. erythropoetic protoporphyria (EPP) and ferrochelatase,

8. Hepatoerythropoetic porphyria (HEP) and uroporphyrinogen decarboxylase or an enzymatically equivalent part or analogue thereof.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

GROUP I

Species 1
Claims 4, 36, 37

Species 2-8
No specific claims

Generic claims: 1, 2, 3, 5, 6, 7, 1, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 35

Group II

Species 1
Claims 38, 40, 41, 42, 43, 44, 45, 46

Species 2-8
No specific claims

Generic claim: 39

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Each of the above 8 species relates to a distinct clinical syndrome and underlying deficiency of a specific enzyme in the eight step synthesis of heme. The deficiency in two diferent syndroms hereditary coproporphyria (HCP) and harderoporphyria (HDP) seems to be related to deffects in one enzyme, coproporphyrinogen oxidase, yet molecular genetics of both syndroms may be not well characterized at this moment.

Thus, each of the species has a special technical feature determined by the deficiency of the specific enzyme; there are eight generic technical features in the instant application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (703) 305-7270. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (703) 308-3804. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 308-0196.

Malgorzata A. Walicka, Ph.D.
Art Unit 1652
Assistant Patent Examiner

REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP ~~1800~~ 1600